

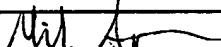
<b>Substitute for form 1449A/PTO</b>  <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b> (use as many sheets as necessary) <b>Sheet 1 of 1</b>	<b>Application Number</b>	Unassigned
	<b>Filing Date</b>	Herewith
	<b>First Named Inventor</b>	Joel Racchini et al.
	<b>Group Art Unit</b>	Unknown
	<b>Examiner Name</b>	Unknown
	<b>Attorney Docket Number</b>	LFS-5015-USNP

## U.S. PATENT DOCUMENTS

Examiner Initials	Cite No. <sup>1</sup>	U.S. Patent Document		Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document mm-dd-yyyy	Pages, Columns, Lines, where relevant passages or relevant figures appear
		Number	Kind Code <sup>2</sup> (if known)			
MA		US-2003/0018300	A1	Duchon et al.	01/23/2003	
MA		US-2003/0060784	A1	Hilgers et al.	03/27/2003	
MA		6,240,306	B1	Rohrschleb et al.	05/29/2001	
MA		6,332,871	B1	Douglas et al.	12/25/2001	

## FOREIGN PATENT DOCUMENTS

Examiner Initials	Cite No. <sup>1</sup>	Foreign Patent Document			Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document mm-dd-yyyy	Pages, Columns, Lines, where relevant passages or relevant figures appear	T <sup>3</sup>
		Office <sup>3</sup>	Number <sup>4</sup>	Kind Code <sup>5</sup>				
MA		WO	01/47408	A1	Roche Diagnostics GmbH	07/05/2001		
MA		WO	02/49507	A1	Inverness Medical Ltd.	06/27/2002		

Examiner Signature		Date Considered	8/4/06
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\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup> Unique citation designation number. <sup>2</sup> See attached Kinds of U.S. Patent Documents. <sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. <sup>6</sup> Applicant is to place a check mark here if English language Translation is attached.

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Approved for use through 10/31/2002. OMB 0651-0031

U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

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## INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(use as many sheets as necessary)

Sheet 1 of 2

<b>Application Number</b>	10/653,023
<b>Filing Date</b>	August 28, 2003
<b>First Named Inventor</b>	Joel Racchini
<b>Group Art Unit</b>	3736
<b>Examiner Name</b>	Unknown
<b>Attorney Docket Number</b>	LFS-5015 USNP

## U.S. PATENT DOCUMENTS

[illegible]

**FOREIGN PATENT DOCUMENTS**

[illegible]

Examiner Signature		Date Considered	9/4/06
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Page <sup>2</sup>~~1~~ of <sup>2</sup>~~1~~

<b>Application Number</b>	10/653,023
<b>Filing Date</b>	August 28, 2003
<b>First Named Inventor</b>	Joel Racchini
<b>Group Art Unit</b>	3736
<b>Examiner Name</b>	Unknown
<b>Attorney Docket Number</b>	LFS-5015 USNP

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Examiner Signature	<i>Mike</i>	Date Considered	8/4/06
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PTO/SB/08A (08-00)

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<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b> (use as many sheets as necessary) Sheet 1 of 5	Substitute for form 1449A/PTO	Application Number	10/653,023
		Filing Date	08/28/2003
		First Named Inventor	Racchini
		Group Art Unit	3736
		Examiner Name	unknown
		Attorney Docket Number	LFS5015USNP

**U.S. PATENT DOCUMENTS**

Examiner Initials	Cite No. <sup>1</sup>	U.S. Patent Document		Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document mm-dd-yyyy	Pages, Columns, Lines, where relevant passages or relevant figures appear
		Number	Kind Code <sup>2</sup> (if known)			
		2003/0018300	A1	Duchen et al.	1/29/03	
MA		2002/0019022	A1	Dunn et al.	2/14/02	
MA		5,956,501		Brown	9/21/99	
MA		6,275,717	B1	Gross et al.	8/14/01	
MA		6,424,847	B1	Mastrototaro et al.	7/23/02	
MA		6,579,690	B1	Bonnecaze et al.	6/17/03	
MA		6,233,471	B1	Berner et al.	5/15/01	
		<del>6,275,717</del>	<del>B1</del>	<del>Kumik</del>	<del>6/7/01</del>	
MA		6,234,990		Kost et al.	5/22/01	
		<del>6,240,366</del>		<del>Gardner et al.</del>	<del>9/29/01</del>	
MA		6,251,083		Roe et al.	6/26/01	

**FOREIGN PATENT DOCUMENTS**

Examiner Initials	Cite No. <sup>1</sup>	Foreign Patent Document			Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document mm-dd-yyyy	Pages, Columns, Lines, where relevant passages or relevant figures appear	T <sup>6</sup>
		Office <sup>3</sup>	Number <sup>4</sup>	Kind Code <sup>5</sup>				
MA		WO	97/07734	A1	Spectrx, Inc., and Altea Technologies, Inc.	3/6/97		
		<del>WO</del>	<del>94/47498</del>	<del>A1</del>	<del>Roche Diagnostics GmbH</del>	<del>7/5/01</del>		
		<del>EP</del>	<del>1260815</del>	<del>A2</del>	<del>LifeScan, Inc.</del>	<del>11/27/02</del>		
		<del>GB</del>	<del>2375053</del>	<del>A</del>	<del>Agilent Technologies, Inc.</del>	<del>11/6/02</del>		

Examiner Signature	<i>MA</i>	Date Considered	8/4/06
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Substitute for form 1449A/PTO

## INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(use as many sheets as necessary)

Sheet 2 of 5

<b>Application Number</b>	10/653,023
<b>Filing Date</b>	08/28/2003
<b>First Named Inventor</b>	Racchini
<b>Group Art Unit</b>	3736
<b>Examiner Name</b>	unknown
<b>Attorney Docket Number</b>	LFS5015USNP

## U.S. PATENT DOCUMENTS

Examiner Initials	Cite No. 1	U.S. Patent Document		Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document mm-dd-yyyy	Pages, Columns, Lines, where relevant passages or relevant figures appear
		Kind Code <sup>2</sup>				
		Number	(if known)			
MA		6,272,364		Kumik	8/7/01	
MA		6,319,210		Grage et al.	11/20/01	
MA		6,329,161		Heller et al.	12/11/01	
		6,332,874		Radwanski	12/25/01	
MA		6,514,718		Heller et al.	2/4/03	
MA		6,558,321		Burd et al.	5/6/03	
MA		6,702,857		Shuts et al.	3/9/04	
MA		5,002,054		Ash et al.	3/26/91	
MA		5,139,023		Stanley et al.	8/18/92	
MA		5,165,418		Tankovich	11/24/92	
MA		5,174,291		Schoonen et al.	12/29/92	
MA		5,231,975		Bommannan et al.	8/3/93	

**FOREIGN PATENT DOCUMENTS**

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Examiner Signature		Date Considered	8/4/06
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**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**

(use as many sheets as necessary)

Sheet 3 of 5

Application Number	10/653,023
Filing Date	08/28/2003
First Named Inventor	Racchini
Group Art Unit	3736
Examiner Name	unknown
Attorney Docket Number	LFS5015USNP

**U.S. PATENT DOCUMENTS**

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		Number	Kind Code <sup>2</sup> (if known)			
MA		5,458,140		Eppstein et al.	10/17/95	
MA		5,706,806		Kissinger	1/13/98	
MA		6,022,316		Eppstein et al.	2/8/00	
MA		6,040,194		Chick et al.	3/21/00	
MA		6,155,992		Henning et al.	12/5/00	
MA		6,232,130		Wolf	5/15/01	
		<del>6,233,471</del>		<del>Remey et al.</del>	<del>3/15/01</del>	
MA		5,582,184		Erickson et al.	12/10/96	
MA		5,746,217		Erickson et al.	5/5/98	
MA		5,820,570		Erickson et al.	10/13/98	
MA		6,080,116		Erickson et al.	6/27/00	
MA		6,203,504	B1	Latterell et al.	3/20/01	

**FOREIGN PATENT DOCUMENTS**

Examiner Initials	Cite No. <sup>1</sup>	Foreign Patent Document			Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document mm-dd-yyyy	Pages, Columns, Lines, where relevant passages or relevant figures appear	T <sup>6</sup>
		Office <sup>3</sup>	Number <sup>4</sup>	Kind Code <sup>5</sup>				

Examiner Signature	<i>Michael A. ...</i>	Date Considered	8/14/06
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# INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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Sheet 4 of 5

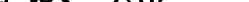
<b>Application Number</b>	10/653,023
<b>Filing Date</b>	08/28/2003
<b>First Named Inventor</b>	Racchini
<b>Group Art Unit</b>	3736
<b>Examiner Name</b>	unknown
<b>Attorney Docket Number</b>	LFS015USNP

## U.S. PATENT DOCUMENTS

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## FOREIGN PATENT DOCUMENTS

[illegible]

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# INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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Sheet 5 of 5

<b>Application Number</b>	10/653,023
<b>Filing Date</b>	08/28/2003
<b>First Named Inventor</b>	Racchini
<b>Group Art Unit</b>	3736
<b>Examiner Name</b>	unknown
<b>Attorney Docket Number</b>	LFS015USNP

## OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS

[illegible]

Examiner Signature		Date Considered	2/4/06
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SUBMISSION UNDER MPEP 609 D  Page 1 of 1	Application Number	10/653,023
	Filing Date	08/28/2003
	First Named Inventor	Racchini
	Group Art Unit	3736
	Examiner Name	unknown
	Attorney Docket Number	LFS5015USNP

#### U.S. PATENT DOCUMENTS

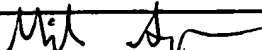
Examiner Initials	Cite No. <sup>1</sup>	Name of Patentee or Applicant of Cited Document	U.S. Patent Document		Pages, Columns, Lines, where relevant passages or relevant figures appear
			Number	Kind Code <sup>2</sup> (if known)	
MA		Sohrab, Borzu	2003/055326	A1	paras.0015-0027, relevant to claims 1,12
MA		Radwanski, Ryszard et al.	2002/082522	A1	paras. 0022-0025,0033- 0040, 0121-0128, 0137- 0139, relevant to claims 1-5, 9-13
MA		Roe, Jeffrey N. et al.	2002/022789	A1	paras. 0094-0099, relevant to claims 1,9,10,13
		<del>Freeman et al.</del>	<del>2003/073931</del>	<del>A1</del>	<del>Relevant to claim 1</del>

#### FOREIGN PATENT DOCUMENTS

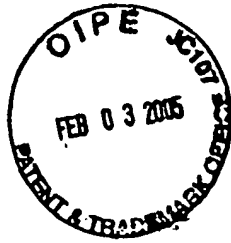
Examiner Initials	Cite No. <sup>1</sup>	Name of Patentee or Applicant of Cited Document	Foreign Patent Document			Pages, Columns, Lines, where relevant passages or relevant figures appear	T <sup>3</sup>
			Office <sup>3</sup>	Number <sup>4</sup>	KindCode <sup>5</sup>		
		<del>LifeScan, Inc.</del>	<del>EP</del>	<del>1260815</del>	<del>A</del>	<del>Relevant to claims 1,3, 10-12, 16</del>	

#### OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS

Examiner 's Initials <sup>6</sup>	Cite No. <sup>1</sup>	Include name of the author (in CAPITOL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published	T <sup>2</sup>
MA		Schmidtke et al., "Measurement and modeling of the transient difference between blood and subcutaneous glucose concentrations in the rat after injection of insulin". Proceedings of the National Academy of Sciences of the United States of America, vol. 95, January 1998 (1998-01), pages 294-299, XP00120307; page 296, column 1-page 298, column 1.	
MA		European Patent Search Report for Application 04255207.5 dated November 17, 2004	
MA		Patent Cooperation Treaty International Search Report,European Patent Office, for Application PCT/US2004/018144, dated October 27, 2004.	

Examiner Signature		Date Considered	8/4/06
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FORM PTO-1449 (Modified)  
LIST OF PATENTS AND PUBLICATIONS  
FOR APPLICANT'S INFORMATION DISCLOSURE STATEMENT  
(Use several sheets if necessary)  
Sheet 1 of 5

In the Application of Racchini, J., et al.

Serial No.: 10/653,023

Art Unit: 3736

Filed: 28 August 2003

Examiner: Robert Nasser

Title: Devices, Systems and Methods for Extracting Bodily Fluid and Monitoring an Analyte Therein

U.S. PATENT DOCUMENTS							
Exam. Init.	Ref. Desig.	Document No.	Date	Name	Class	Sub Class	Filing Date
MA	AA-1	5,279,543	18 JAN 1994	Glikfeld et al.	604	20	4/30/92
↑	AA-2	5,362,307	8 NOV 1994	Guy et al.	604	20	10/4/91
	AA-3	5,730,714	24 MAR 1998	Guy et al.	604	20	9/26/94
	AA-4	5,735,273	7 APR 1998	Kurnik et al.	128	635	9/12/95
	AA-5	5,771,890	30 JUN 1998	Tamada	128	635	6/24/94
	AA-6	5,827,183	27 OCT 1998	Kurnik et al.	600	345	10/29/97
	AA-7	5,954,685	21 SEP 1999	Tierney	604	20	5/24/96
	AA-8	6,023,629	8 FEB 2000	Tamada	600	347	11/10/97
	AA-9	6,141,573	31 OCT 2000	Kurnik et al.	600	345	8/4/98
	AA-10	6,144,869	7 NOV 2000	Berner et al.	600	347	5/11/99
↓	AA-11	6,180,416	30 JAN 2001	Kurnik et al.	436	518	9/30/98
MA	AA-12	6,201,979	13 MAR 2001	Kurnik et al.	600	345	3/13/00
	AA-13	<del>6,233,471</del>	<del>15 MAY 2001</del>	<del>Berner et al.</del>	<del>600</del>	<del>345</del>	<del>5/11/99</del>
	AA-14	<del>6,272,364</del>	<del>7 AUG 2001</del>	<del>Kurnik</del>	<del>600</del>	<del>345</del>	<del>5/11/99</del>

Examiner: MA

Date Considered: 8/4/06

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FORM PTO-1449 (Modified)  
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(Use several sheets if necessary)  
Sheet 2 of 5

In the Application of Racchini, J., et al.

Serial No.: 10/653,023

Art Unit: 3736

Filed: 28 August 2003

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Title: Devices, Systems and Methods for Extracting Bodily Fluid and Monitoring an Analyte Therein

U.S. PATENT DOCUMENTS							
Exam. Init.	Ref. Desig.	Document No.	Date	Name	Class	Sub Class	Filing Date
MA	AA-15	6,298,254	2 OCT 2001	Tamada	600	347	11/1/99
↑	AA-16	6,299,578	9 OCT 2001	Kurnik et al.	600	309	9/18/97
	AA-17	6,309,351	30 OCT 2001	Kurnik et al.	600	309	8/28/00
	AA-18	6,326,160	4 DEC 2001	Dunn et al.	435	14	9/27/99
	AA-19	6,341,232	22 JAN 2002	Conn et al.	604	20	3/16/01
	AA-20	6,356,776	12 MAR 2002	Berner et al.	600	347	8/16/00
	AA-21	6,370,410	9 APR 2002	Kurnik et al.	600	345	1/18/01
	AA-22	6,393,318	21 MAY 2002	Conn et al.	604	20	5/11/99
	AA-23	6,438,414	20 AUG 2002	Conn et al.	604	20	11/30/01
	AA-24	6,529,755	4 MAR 2003	Kurnik et al.	600	345	12/6/01
	AA-25	6,542,765	1 APR 2003	Guy et al.	600	345	3/10/98
	AA-26	6,546,269	8 APR 2003	Kurnik	600	345	1/5/01
↓	AA-27	6,561,978	13 MAY 2003	Conn et al.	600	309	2/11/00
MA	AA-28	6,587,705	1 JUL 2003	Kim et al.	600	347	3/10/99

Examiner: Mil [Signature]

Date Considered: 8/4/06

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FORM PTO-1449 (Modified)  
LIST OF PATENTS AND PUBLICATIONS  
FOR APPLICANT'S INFORMATION DISCLOSURE STATEMENT  
(Use several sheets if necessary)  
Sheet 3 of 5

In the Application of Racchini, J., et al.

Serial No.: 10/653,023

Art Unit: 3736

Filed: 28 August 2003

Examiner: Robert Nasser

Title: Devices, Systems and Methods for Extracting Bodily Fluid and Monitoring an Analyte Therein

U.S. PATENT DOCUMENTS							
Exam. Init.	Ref. Desig.	Document No.	Date	Name	Class	Sub Class	Filing Date
MA	AA-29	6,594,514	15 JUL 2003	Berner et al.	600	347	12/20/01
↑	AA-30	6,595,919	22 JUL 2003	Berner et al.	600	365	2/27/01
↑	AA-31	6,653,091	25 NOV 2003	Dunn et al.	435	14	7/23/01
↑	AA-32	6,687,522	3 FEB 2004	Tamada	600	347	6/28/01
↓	AA-33	6,714,815	30 MAR 2004	Guy et al.	604	20	1/13/03
MA	AA-34	6,736,777	18 MAY 2004	Kim et al.	600	365	1/29/03
	AA-35	6,319,210	20 NOV 2001	Douglas, et al.	600	583	6/5/00
	AA-36	6,332,871	25 DEC 2001	Douglas, et al.	600	583	5/10/99
MA	AA-37	6,464,699	15 OCT 2002	Swanson	606	41	3/24/00

FOREIGN PATENT DOCUMENTS							
Exam. Init.	Ref. Desig.	Document No.	Publication Date	Country or Patent Office	Class	Sub Class	Translation YES NO
	AB-1						

Examiner: 

Date Considered: 8/4/06

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Art Unit: 3736

Filed: 28 August 2003

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Title: Devices, Systems and Methods for Extracting Bodily Fluid and Monitoring an Analyte Therein

OTHER DOCUMENTS (including Author, Title, Date, Pertinent Pages, etc.)		
Exam. Init.	Ref. Desig.	Description
MA	AC-1	Chase, HP., et al., "Use of the GlucoWatch® Biographer in Children with Type 1 Diabetes", Pediatrics, 111(4):790-794 (2003)
↑	AC-2	Eastman, RC., et al., "Use of the GlucoWatch® Biographer in Children and Adolescents with Diabetes", Pediatric Diabetes, 3:127-134 (2002)
	AC-3	Erickson, D., "Skinside Out", Scientific American, November pages 128&130 (1991).
	AC-4	Garg, SK., et al., "Correlation of Fingerstick Blood Glucose Measurements with GlucoWatch™ Biographer Glucose Results in Young Subjects with Type 1 Diabetes", Diabetes Care, 22(10):1708-1714 (1999)
	AC-5	Glikfeld, P., et al., "Noninvasive Sampling of Biological Fluids by Iontophoresis", Plenum Publishing Corporation, 6(11):988-990 (1989).
	AC-6	Kurnik, R., et al., "Application of the Mixtures of Experts Algorithm for Signal Processing in a Non-invasive Glucose Monitoring System", Sensors and Actuators., 60(1):19-26 (1999).
	AC-7	Kurnik, R., et al., "Design and Simulation of a Reverse Iontophoretic Glucose Monitoring Device", J Electrochem Soc., 145(12):4119-4125 (1998).
	AC-8	Pitzer, KR., et al., "Detection of Hypoglycemia with the GlucoWatch® Biographer", Diabetes Care, 24(5):881-885 (2001)
	AC-9	Potts, R., et al., "Glucose Monitoring by Reverse Iontophoresis", Diabetes Metab Res Rev., 18(suppl 1):s49-s53 (2002).
	AC-10	Rao, G., et al., "Iontophoretic and Noninvasive Glucose Monitoring, Proceed Intern. Symp. Control Rel. Bioact. Mater., 21:13-14 (1994).
↓	AC-11	Tamada, J., et al., "Measurement of Glucose in Diabetic Subjects Using Non-invasive Transdermal Extraction", Nature Medicine, 1(11):1198-1201 (1995)
MA	AC-12	Tamada, JA., et al., "Keeping Watch on Glucose", IEEE Spectrum, Apr: pages 52-57 (2002)

Examiner: M. J. [Signature]

Date Considered: 8/4/06

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Sheet 5 of 5

In the Application of Racchini, J., et al.

Serial No.: 10/653,023

Art Unit: 3736

Filed: 28 August 2003

Examiner: Robert Nasser

Title: Devices, Systems and Methods for Extracting Bodily Fluid and Monitoring an Analyte Therein

OTHER DOCUMENTS (including Author, Title, Date, Pertinent Pages, etc.)		
Exam. Init.	Ref. Desig.	Description
MA	AC-13	Tamada, JA., et al., "Noninvasive Glucose Monitoring: Comprehensive Clinical Results", JAMA, 282(19):1839-1844 (1999)
↑	AC-14	Tierney, M., "Transdermal Glucose Monitoring Opens a New Age of Diabetes Management", IVD Technology, 9(4):51-56 (2003)
	AC-15	Tierney, M., et al., "A Non-invasive Glucose Monitor: The GlucoWatch® Biographer", The Biochemist, 23(6):17-19 (2001).
	AC-16	Tierney, M., et al., "Clinical Evaluation of the GlucoWatch® Biographer: A Continual, Non-invasive Glucose Monitor for Patients with Diabetes", Biosensors & Bioelectronics, 16:621-629 (2001).
	AC-17	Tierney, M., et al., "Effect of Acetaminophen on the Accuracy of Glucose Measurements Obtained with the GlucoWatch Biographer", Diabetes Technology & Therapeutics, 2(2):199-207 (2000)
	AC-18	Tierney, M., et al., "Electroanalysis of Glucose in Transcutaneously Extracted Samples", Electroanalysis, 12(9):666-671 (2000)
↓	AC-19	Tierney, M., et al., "The GlucoWatch® Biographer: A Frequent, Automatic and Noninvasive Glucose Monitor", Annals Med, 32(9):632-641 (2000)
MA	AC-20	Uhegbu, C., et al., "Management of Interferences in a Transdermal, Noninvasive Glucose Monitoring Device", Clinical Chemistry, 45(9):1679-1681 (1999)

Examiner: MA MA

Date Considered: 8/4/06

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# INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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Sheet 1 of 1

<b>Application Number</b>	10/653,023
<b>Filing Date</b>	August 28, 2003
<b>First Named Inventor</b>	Joel RACCHINI
<b>Group Art Unit</b>	3736
<b>Examiner Name</b>	Robert L. NASSER
<b>Attorney Docket Number</b>	LFS-5015USNP

## U.S. PATENT DOCUMENTS

[illegible]

**FOREIGN PATENT DOCUMENTS**

[illegible]

Examiner Signature	<i>M. L. A.</i>	Date Considered	8/4/06
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<b>Attorney Docket Number</b>	LFS-5015USNP

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## FOREIGN PATENT DOCUMENTS

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